REMARKS

35 U.S.C. §112, first paragraph

The rejection of Claims 23-30 under 35 U.S.C. §112, first paragraph, for failing to comply with the written description requirement is respectfully traversed. The Examiner writes that the specification only discloses a single dosage form i.e. a soft gelatin capsule containing the active ingredients. It is respectfully submitted that the Applicants' specification clearly discloses the use of both multiple and different dosage forms, as is supported by the Declaration under 37 C.F.R. § 1.132 filed herewith.

The specification, as is clearly seen in paragraph 95, encompasses the use of varying dosage forms. The use of dosage forms other that gelatin capsules, more specifically tablets, is clearly intended and envisioned by those skilled in the art.

> "The present inventive subject matter contemplates the use of pharmaceutically acceptable carriers with may be prepared from a wide range of materials. Without being limited thereto, such materials include…binders and adhesives…disintegrants…" (See paragraph 96.)

It is well known to those skilled in the art that binders, including the binders listed in paragraph 97, as well as adhesives and disintegrants, are for use in tablet dosage forms, not gelatin capsules. Binders and adhesives are utilized to hold the tablets together, and disintegrants are used to help the tablets break apart and release API's after tablet ingestion.

Further, the bulking substances listed in paragraph 97 are not generally used in gelatin capsules. These bulking agents include sugar, lactose, gelatin, starch and silicon dioxide. In addition, it is well known that several of the plasticizers listed in paragraph 98, including diethyl phthalate, diethyl sebacate, triethyl citrate, cronotic acid, butyl phthalate and dibutyl sebacate are incompatible with use in a gelatin capsule.

Therefore, by the inclusion of multiple components that are only compatible with a tablet formulation, it is submitted that the use of tablet formulations is fully supported by the specification. It is respectfully requested that the rejection of Claims 23-30 under 35 U.S.C. §112, first paragraph, for failing to comply with the written description requirement be withdrawn.

35 U.S.C. §102(b) or 35 U.S.C. §103(a)

The rejection of Claims 23-28 as being anticipated under 35 U.S.C. §102(b) or, in the alternative, under 35 U.S.C. §103(a) as being obvious over WO 97/04668 (U.S. Patent No. 6,471,969) is respectfully traversed.

U.S. Patent No. 6,471,969 (hereinafter the '969 patent) discloses and claims a two-phase preparation for use at differential times. Product A is a gelatin capsule disclosed to be for use at the beginning of the day phase, or active phase, and product B is a gelatin capsule for use at the beginning of the night phase, or regenerative phase of the human metabolism. (See Col. 5, starting at line 9.) Further, as is clearly seen in Claim 1 of the '969 patent, both product A and product B are required to include an unsaturated fatty acid.

The Applicants' claimed composition comprises two dosage forms, one which includes an EFA and one that includes calcium. Further, the Applicants' clearly intend the dosage forms

to be ingested at the same time. There is no language in the claims that the two dosage forms are to be administered at different times, as is required by the '969 patent. By requiring two gelatin capsule dosage forms, each including unsaturated fatty acids, that must be taken at different times, the '969 patent teaches directly against the Applicants' composition as claimed.

It is therefore requested that the rejection of Claims 23-28 as being anticipated under 35 U.S.C. §102(b) or, in the alternative, under 35 U.S.C. §103(a) as being obvious over WO 97/04668 (U.S. Patent No. 6,471,969) be withdrawn.

If any issue regarding the allowability of any of the pending claims in the present application could be readily resolved, or if other action could be taken to further advance this application such as an Examiner's amendment, or if the Examiner should have any questions regarding the present amendment, it is respectfully requested that the Examiner please telephone Applicants' undersigned attorney in this regard.

Respectfully submitted,

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